

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

**Rejection for Lack of Written Description**

Applicants contend that the present specification provides sufficient written description support for the term ester. For instance, the compounds of Formula I are expressly denoted to include "a pharmaceutically acceptable salt, ester or solvate thereof." See page 18, line 11. Table I at page 54-56 includes nineteen compounds that are esters, Table II, pages 58-59, includes eight ester compounds and Table IV, pages 60-61, includes nine ester compounds.

According to MPEP § 2163.02, "[a]n objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Applicants contend that anyone of skill in the art would be able to recognize that applicants did invent what is claimed, that is "a pharmaceutically acceptable salt or ester" of a compound of Formula 1. See also MPEP Section 2163.03, which states:

While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. (Emphasis added.)

Thus, it is incumbent upon the Examiner to present reasons of lack of written description that will overcome a strong presumption of adequate written description. As MPEP § 2163.03 discusses, written description is shown by whether the disclosure of the application "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570,

1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). The same section of the MPEP states "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Therefore, applicants contend they have met the threshold requirement of written description and request withdrawal of the rejections for lack of written description.

### **Rejection for Indefiniteness**

Applicants request that the rejection for indefiniteness be withdrawn for the following reasons. According to MPEP§ 2173.02, the test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

This same section of the MPEP notes that a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence"). See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles....Only when a claim remains insolubly ambiguous without a discernible

meaning after all reasonable attempts at construction must a court declare it indefinite.")

(Emphasis added.)

Applicants contend that the term ester would be understood by one of skill in the art. In fact, even one who has completed a first year undergraduate level course in organic chemistry would understand what is meant by the term ester. See Appendix I, providing the definition of ester from a college level introduction to organic chemistry textbook, *Organic Chemistry*, 6<sup>th</sup> ed., Morrison & Boyd, Prentice Hall, 1992. Therefore, one of ordinary skill in the art could readily interpret the claims to understand if a chemical compound was an ester of a compound of Formula I, claim 1.

To further evidence that the term ester is not indefinite, applicants attach two database searches conducted on claims of US patents. One search, attached as Appendix II, shows that between January 1, 1999 and November 1, 1999, 387 US patents issued with claim language of "pharmaceutically acceptable w/2 ester thereof". Another search, Appendix III, shows that between January 1, 1990 and November 1, 1999, 1103 US patents issued with claim language of "pharmaceutically acceptable w/2 ester thereof". The fact that this terminology is present in over one thousand issued US patents demonstrates that one of ordinary skill would understand the phrase pharmaceutically acceptable ester. Therefore, it is not possible to conclude that the term ester is "insolubly ambiguous without a discernible meaning" to one of skill in the art.

Applicants further contend the MPEP § 2173.05 explicitly permits double inclusion language in Markush groups.

Similarly, the double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, "selected from the group consisting of amino, halogen, nitro, chloro and alkyl" should be acceptable even though "halogen" is generic to "chloro." (Emphasis added.)

Applicants also note that MPEP § 2173.02 explicitly states that there is no *per se* rules against exemplary claim language.

For example, a claim recites "a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc." The mere use of the phrase "such as" in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms "suitable liquid" and "solids of a filtering agent" in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. (MPEP § 2173.02, emphasis in original)

Therefore, applicants urge that the rejection for indefiniteness is improper and should be withdrawn.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.


Respectfully submitted,

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